Complete Summary

GUIDELINE TITLE

Colorectal cancer screening.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Colorectal cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jun. 50 p. [71 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Colorectal cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Jun. 57 p.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Colorectal cancer

GUIDELINE CATEGORY

Evaluation
Prevention
Risk Assessment
Screening

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To increase the percentage of people aged 50 to 80 who are up-to-date with colorectal screening
- To increase patient participation in screening for colorectal cancer
- To increase the percent of positive colorectal cancer screening tests that have follow-up tests
- To reduce wasteful, unproductive processes for colorectal cancer screening

TARGET POPULATION

Patients meeting all of the following criteria for routine screening for colorectal cancer:

- 50 to 80 years old or if African American 45 to 80 years old
- No personal history of polyps and/or colorectal cancer
- No family history of colorectal cancer in one first order relative diagnosed before age 60, or two first order relatives diagnosed at any age
- No family history of adenomatous polyps in one first order relative diagnosed before age 60

INTERVENTIONS AND PRACTICES CONSIDERED

1. Prescreening education and counseling
2. Risk assessment and determination of need for increased risk surveillance
3. Colonoscopy
4. Barium enema (double contrast barium enema [DCBE], fluoroscopic barium enema)
5. Flexible sigmoidoscopy
6. Fecal occult blood test (FOBT)
7. Digital rectal examination (DRE)
8. Biopsy
9. Computed tomographic (CT) colonography

MAJOR OUTCOMES CONSIDERED

- Incidence of and mortality rates from colorectal cancer
- Cost-effectiveness of screening measures
- Adverse effects of screening measures
- Sensitivity and specificity of screening tests for colorectal cancer

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study

- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary, and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Preventive Services Steering Committee carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occur throughout the pilot test phase, which usually lasts for three months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Preventive Services Steering Committee reviews the revised guideline and approves it for implementation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): In addition to updating their clinical guidance, ICSI has developed a new format for all guidelines. Key additions and changes include: combination of the annotation and discussion section; the addition of "Key Points" at the beginning of most annotations; the

inclusion of references supporting the recommendations; and a complete list of references in the Supporting Evidence section of the guideline. For a description of what has changed since the previous version of this guidance, refer to "Summary of Changes -- June 2006."

The recommendations for colorectal cancer (CRC) screening are presented in the form of 2 algorithms with a total of 34 components and accompanied by detailed annotations. Algorithms are provided for: Screening and Flexible Sigmoidoscopy/Total Colon Evaluation (TCE). Clinical highlights and selected annotations (numbered to correspond with the algorithms) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III, Not Assignable) definitions are repeated at the end of the "Major Recommendations" field.

Clinical Highlights

- Screening criteria for this guideline includes:
- The patient must meet all four of the following criteria:
    - 50 to 80 years old or if African American 45 to 80 years old
    - No personal history of polyps and/or colorectal cancer
    - No family history of colorectal cancer in:
        - one first-order relative diagnosed before age 60 or
        - two first order relatives diagnosed at any age
    - No family history of adenomatous polyps in one first-order relative diagnosed before age 60.

(A single first-order relative diagnosed with colorectal cancer after age 60 may put the patient at a slightly increased risk and may warrant starting colon cancer screening at age 40. A single first-order relative with an adenomatous polyp diagnosed after age 60 may put the patient at a slightly increased risk and may also warrant starting colon cancer screening at age 40).

(Annotation #3)

- Colorectal cancer screening is recommended for all patients 50 to 80 years of age, using one of the following methods based on joint decision making by patient and provider:
    - Flexible sigmoidoscopy every 5 years
    - Annual fecal occult blood test (FOBT)
    - Combination of flexible sigmoidoscopy or colonoscopy every 5 years and annual FOBT
    - Total colon evaluation as defined in the guideline

    (Annotation #6)

Screening Algorithm Annotations

1. Prescreening Education and Counseling

    This guideline represents its work group's contribution to colorectal cancer screening and must be seen within the larger context of all preventive health

activities. The work group acknowledges the important role played by education and outreach efforts in helping to increase the number of risk-appropriate individuals who present themselves for colorectal cancer screening, thereby increasing the rate of early detection of this disease.

2. Prevention Opportunity

A prevention opportunity may be any visit to a provider which provides the opportunity for conducting the screening process, a preventive services visit, and outreach to patients who historically do not come in for visits.

3. Meets Screening Criteria?

Since the term "screening" implies random testing of asymptomatic individuals within a population, patients who are symptomatic or who have a history of gastrointestinal symptoms or disease may be excluded from this screening activity. Providers must make an individual decision on a case-by-case basis.

The best data available support screening between ages 50 and 80; however, otherwise healthy individuals over the age of 80 may be candidates for continued screening if their presumed life expectancy is 8 or more years.

The patient must meet all four of the following criteria:

- 50 to 80 years old or if African American 45 to 80 years old
- No personal history of polyps and/or colorectal cancer
- No family history of colorectal cancer in:
    - one first order relative diagnosed before age 60 or
    - two first-order relatives diagnosed at any age
- No family history of adenomatous polyps in one first-order relative diagnosed before age 60.

(A single first-order relative diagnosed with colorectal cancer after age 60 may put patients at a slightly increased risk and may warrant starting colon cancer screening at age 40. A single first-order relative with an adenomatous polyp diagnosed after age 60 may put the patient at a slightly increased risk and may also warrant starting colon cancer screening at age 40).

Evidence supporting this recommendation is of classes: M, R

4. Increased Risk for Development of Colorectal Cancer?

Patients with the following history are considered to be at increased risk:

- Prior polyp (adenoma with villous component, or any adenomatous polyp greater than 10 mm)
- Prior colorectal cancer
- Long standing inflammatory bowel disease involving the colon
- Family history of colorectal cancer involving:
    - One first order relative* diagnosed before age 60

- Two first order relatives* diagnosed at any age
- A single first order relative diagnosed after age 60 may put patients at a very slightly increased risk.

*First order relatives include only parents, siblings, and children.

Certain patients are considered to be at high risk for development of colorectal cancer. Relevant conditions include familial polyposis coli and variants, long-standing chronic ulcerative colitis, and non-polyposis hereditary colorectal cancer. Surveillance of patients with these disorders lies outside the scope of this screening guideline.

Evidence supporting this recommendation is of classes: B, C, D, R

5. Increased Risk Surveillance

Patients at increased risk of developing colorectal cancer as indicated in Annotation #4 "Increased Risk for Development of Colorectal Cancer?" require colonoscopic surveillance at a 3- to 5-year interval, and are outside the scope of this guideline.

Whenever colonoscopy is utilized, it should begin at age 50 or 10 years before the index carcinoma, whichever comes first. Follow-up intervals should be dictated by the results of colonoscopy but should occur at least every five years.

Patients with only one first order relative with a history of colorectal cancer diagnosed after the age of 60 could be followed using combined barium enema and flexible sigmoidoscopy at five-year intervals. The U.S. Multisociety Task Force on Colorectal Cancer recommends starting screening in these patients at age 40, the American Cancer Society recommends starting at age 50.

6. Patient and Provider Choose Screening Test Pathway

Screening intervals apply to patients between 50 and 80 years old or age 45 for African Americans without clinical factors that place them at increased risk for colorectal cancer. Clinical groups may decide internally as to which screening pathway will be offered routinely at their site. Alternatively, individual clinicians may advise each patient as to which pathway might be most suitable and, with the patient's preference in mind, choose one of the pathways recommended in subsequent annotations. Practitioners should keep in mind that colonoscopy involves a higher risk of perforation than flexible sigmoidoscopy. If conscious sedation is used, there is risk of complications related to medication as well as a requirement for a period of post-procedure recovery and providing a driver for transport home after the procedure.

Annual or biannual routine fecal occult blood tests (FOBT) done for large, average risk, randomly selected populations reduce mortality rates for colorectal cancer. [Conclusion Grade I: See Conclusion Grading Worksheet A -- Annotations #6 & 8 (FOBT) in the original guideline document].

When a provider suggests FOBT and/or flexible sigmoidoscopy/Total Colon Exam the patient should be involved in the decision. The patient should be shown the choices involved and should receive information and/or advice on what the test can and cannot prove. The patient should also be informed as to what the follow-up on a positive FOBT might involve.

Fecal occult blood tests (FOBT), even when combined with flexible sigmoidoscopy, fail to detect colorectal cancer in at least 24% of those with cancer. [Conclusion Grade II: See Conclusion Grading Worksheet B -- Annotations #6 & 8 (FOBT & Flexible Sigmoidoscopy) in the original guideline document].

Flexible Sigmoidoscopy versus Fecal Occult Blood Test (FOBT)

At this time, the choice of using one (or both) of these tests should be made on the judgment of the clinician, taking into account other significant factors discussed in the original guideline document, including informed patient choice. In particular, attention is directed to the high rate of false-positive FOBTs and the failure of flexible sigmoidoscopy alone to screen the entire colon.

As yet unproven is which screening test leads to the most efficient and effective use of colonoscopy.

The guideline work group did not see sufficient evidence to reach absolute consensus as to which screening test is preferable, but does advocate screening by one of the four methods delineated. Many in the work group favored flexible sigmoidoscopies over FOBTs for the reasons discussed elsewhere. In recommending choice, the work group is basically in accord with the recommendation of the United States Preventive Services Task Force and the National Institute of Health (NIH).

The time interval for the development of malignant changes in adenomatous polyps is estimated at 5 to 25 years. Therefore, the work group has reached a conservative decision to recommend repeating the flexible sigmoidoscopy or colonoscopy screening at five-year intervals. Some authors suggest that ten-year intervals would be adequate.

Flexible sigmoidoscopy or colonoscopy exams done between the ages of 76 and 79 make repeat exams after age 80 unnecessary. It is the opinion of the work group that the potential survival benefit conferred by the early detection of adenomatous polyps is not realized due to the steep increase in mortality due to concurrent conditions unrelated to colon cancer.

Controlled trials have shown that a simple reminder phone call can decrease the number of missed patient appointments (increase uptake).

Total Colon Evaluation

If, in the judgment of the provider, an examination of the whole colon and rectum is desired, this can be accomplished by either colonoscopy, flexible

sigmoidoscopy combined with fluoroscopic barium enema or double contrast barium enema (DCBE), or computed tomography (CT) colonography. If the sigmoid is not well visualized on DCBE, a flexible sigmoidoscopy should be obtained. The interval between exams within this choice is 5 years (5 to 10 years for colonoscopy). None of these strategies, however, are supported by direct evidence that they reduce mortality from colorectal cancer.

Colonoscopy involves a higher risk of perforation than flexible sigmoidoscopy. If conscious sedation is used, there is risk of complications related to medication as well as a requirement for a period of post-procedure recovery and providing a driver for transport home after the procedure.

Evidence supporting this recommendation is of classes: A, B, C, D, M

8. Patient Submits 3 FOBT Test Slides

A minimum of 3 FOBT cards should be submitted by a patient annually. Fecal immunochemical testing is an acceptable method of testing for occult blood and has a greater sensitivity than guaiac-based methods.

Standard protocols for obtaining specimens should be followed as specified by the manufacturer and/or individual testing lab (usually based on 2 samples from 3 different stool specimens). Slide rehydration is not recommended.

Annual or biannual routine FOBT done for large, average risk, randomly selected populations reduce mortality rates for colorectal cancer [Conclusion Grade I: See Conclusion Grading Worksheet A -- in the original guideline document -- Annotations #6 & 8 (FOBT)]

Evidence supporting this recommendation is of classes: A, C, D, R, X

10. Combination of 60 cm Flexible Sigmoidoscopy Every 5 Years and FOBT Annually

Refer to Annotations #6 and 8 for information on FOBT. Refer to Annotation #11 for information on flexible sigmoidoscopy. When this pathway is chosen, the FOBT should be completed before the flexible sigmoidoscopy.

11. 60 cm Flexible Sigmoidoscopy Every 5 Years

Direct examination of the colon is recommended using a 60 cm flexible sigmoidoscope, preferably with the capacity for performing a biopsy. A digital rectal examination (DRE) may be performed just prior to insertion of the scope.

Suggested minimal preparation may include two phosphasodyl enemas (e.g., Fleet's) on the morning of the procedure and nothing by mouth for four to six hours prior to the procedure. Special attention may need to be directed to the diabetic patient who has not had anything by mouth or the patient on anticoagulation therapy.

Mortality from colorectal cancer can be decreased by flexible sigmoidoscopy examination every 5 years. Additionally, a distal villous or tubulovillous adenoma increases the likelihood of an advanced neoplasm [Conclusion Grade III: See Conclusion Grading Worksheet C in the original guideline document -- Annotation #11 (Flexible Sigmoidoscopy)]

Digital Rectal Exam (DRE)

Separate health care encounters for the sole purpose of doing a DRE are not suggested. A DRE might be performed as part of a visit for either health evaluation or illness-related concerns. This work group acknowledges the American Cancer Society recommendations for annual digital rectal exams (DREs) in persons between the ages of 40 and 49. However, given the extremely low age-specific incidence rates (less than 30 per 100,000) and estimate that only approximately 10% of adenomas and cancers are within reach of the examining finger on DRE, this group has concluded that the theoretical benefit of DRE is insufficient to warrant mandatory annual testing.

Evidence supporting this recommendation is of classes: C, R

13. Total Colon Evaluation (TCE)

Colonoscopy

Colonoscopy, which can visualize the entire colon, is analogous in performance to flexible sigmoidoscopy which has been shown to reduce colorectal cancer mortality.

National consensus guidelines suggest an interval of 10 years between colonoscopy examinations for the average risk population.

Colonoscopy has been shown to reduce the incidence of colorectal cancer in a population of patients with adenomatous polyps. There is, however, no evidence of reduction of colorectal cancer mortality in an average risk population by randomized trial, nonrandomized trial, or case-control studies through the use of colonoscopy, as no studies have been published directly addressing the question. Cost-effectiveness estimates suggest a possible benefit. [Conclusion Grade IV: See Conclusion Grading Worksheet D-- in the original guideline document -- Annotation #13 (Colonoscopy)]

Evidence supporting this recommendation is of class: C

Barium Enema

Barium enema may be performed with either double contrast technique (DCBE) or a fluoroscopic barium enema study conducted by a radiologist with advanced specialized training in gastrointestinal procedures. The fluoroscopic barium enema is performed in conjunction with a proctoscopy or flexible sigmoidoscopy.

There are no studies evaluating whether screening by barium enema alone reduces mortality from colorectal cancer in people at average risk for the disease. This option is based on evidence that screening double contrast barium enemas can image the entire colon and detect cancers and large polyps almost as well as colonoscopy or flexible sigmoidoscopy. [Conclusion Grade III: See Conclusion Grading Worksheet E in the original guideline document -- Annotation #13 (DCBE)]

Evidence supporting this recommendation is of class: C

Computed Tomographic (CT) Colonography

During the last decade, CT colonography (sometimes referred to as virtual colonoscopy) has been developed in the hope that it will eventually provide a non-invasive total colon evaluation with accuracy similar to colonoscopy. Currently, however, CT colonography is being performed and reimbursed as a colorectal cancer screening procedure at only a few sites.

An argument can be made in favor of CT colonography over FOBT and flexible sigmoidoscopy since colonography allows total colon evaluation. The other nationally approved radiographic method of total colon evaluation, double contrast barium enema (DCBE), has been shown to be inferior to CT colonography for polyp detection in over 800 asymptomatic persons at greater than average risk for colorectal cancer.

However, the more important question is the performance of CT colonography in a screening population in comparison to colonoscopy. Research studies comparing CT colonography and colonoscopy have yielded inconsistent results.

Currently, CT colonography seems to be a reasonable colonic imaging examination in the following clinical situations: 1) after incomplete screening or diagnostic colonoscopy; 2) in anticoagulated patients who cannot safely discontinue anticoagulation therapy; 3) patients who refuse colonoscopy and understand that their insurance may or may not cover the cost of the CT. If polyps or other pathology is seen on CT colonography this may require further evaluation with colonoscopy. Only some of these indications are reimbursed by Medicare. In many locations, CT colonography is not available and barium enema can be performed in the situations described above.

Evidence supporting this recommendation is of class: C

Flexible Sigmoidoscopy/Total Colon Evaluation (TCE) Algorithm Annotations

16. Exam Adequate?

Flexible Sigmoidoscopy

The adequacy of a flexible sigmoidoscopy exam is determined by the provider. Reasons for which an exam could be inadequate include:

- Inadequate bowel prep
- Limited distance of scope insertion due to patient discomfort
- Other technical difficulties
- Uncertainty as to the significance of findings
- Unsuccessful biopsy

Barium Enema

The adequacy of a barium enema is determined by the provider. Reasons for which an exam could be inadequate include:

- Inadequate bowel prep
- Inadequate evaluation of recto-sigmoid
- Other technical difficulties
- Uncertainty as to the significance of findings

The provider may reschedule the examination with an altered bowel preparation and suggest a proctoscopy, flexible sigmoidoscopy, or colonoscopy depending on the nature of the findings and/or limitations of the study.

CT Colonography

The adequacy of a CT colonography is determined by the provider. Reasons for which an exam could be inadequate include:

- Inadequate bowel prep
- Other technical difficulties
- Uncertainty as to the significance of findings

The provider may reschedule the examination with an altered bowel preparation and suggest flexible sigmoidoscopy or colonoscopy depending on the nature of the findings and/or limitations of the study.

Colonoscopy

See Annotation #24, "Colonoscopy Exam Adequate?"

17. Schedule Re-Exam

A re-examination could be performed immediately after adequate prepping or at the discretion of the provider, dependent on individual patient factors.

18. Positive Findings?

A positive finding on screening includes an invasive cancer, polyp, bleeding source, or mucosal abnormality. From the standpoint of colorectal cancer screening, diverticula, small left sided hyperplastic polyps, and a single tubular adenoma less than 10 mm are not precursors to cancer. Large right sided hyperplastic polyps particularly those that fit the description of sessile serrated adenomas may be precursors to cancer and additional follow-up may

be warranted. There currently are no published or society endorsed guidelines regarding follow up of concerning hyperplastic polyps. Characteristics of hyperplastic polyps that should raise concern are multiple hyperplastic polyps proximal to the sigmoid colon (greater than 5 mm), large size (greater than 10 mm), a family history of hyperplastic polyposis syndrome, or a family history of colon cancer. Follow-up of these patients at this point is individualized but should be at least as aggressive as follow up for patients with adenomatous polyps. As a frame of reference, a standard biopsy forceps fully opens to a diameter of 7 mm. Other authors include tubular adenomas less than 10 mm in the same risk category as hyperplastic polyps.

Evidence supporting this recommendation is of classes: B, C

21. Adenomatous Polyp?

Attempt biopsy of every polyp under 5 mm in diameter. Polyps larger than 10 mm should be referred for complete excision at colonoscopy (no biopsy needed). Intermediate-sized polyps (greater than 5 mm and less than 10 mm) may be referred for colonoscopic removal. If the polyp was biopsied at flexible sigmoidoscopy and is hyperplastic on histology, no further exam is needed at this screening. Nonadenomatous polyps (juvenile, hyperplastic, lipomatous, inflammatory) have no precancerous potential and do not require referral for colonoscopy.

Completion of a biopsy may be dependent upon the operator's comfort or skill level. If a biopsy is indicated but not performed, the patient should be referred.

24. Colonoscopy Exam Adequate?

The decision with respect to the adequacy of a colonoscopy is at the discretion of the provider. Reasons for which an exam would be inadequate include:

- Inadequate bowel prep
- Limited distance of scope insertion due to patient discomfort
- Other technical difficulties
- Uncertainty as to the significance of findings
- Unsuccessful biopsy

26. Radiologic Exam

The colonoscopy exam may be inadequate for a number of reasons. The preparation of the colon may be inadequate for an accurate exam. If this is the case, the patient should be re-prepped with an alternate or more vigorous preparation method and the colonoscopy repeated.

If the colonoscopy is inadequate due to a partially obstructing lesion that precludes a more proximal advance of the colonoscope, the more proximal colon should be evaluated by radiologic means. In those locations where CT colonography is available, this test has been shown to provide more accurate

examination of the proximal colon than air contrast barium enema. If CT colonography is not available, use of a contrast enema to evaluate the more proximal colon is advised.

Evidence supporting this recommendation is of classes: C, D

31. Confirmed Diagnosis of Colorectal Cancer?

    Positive pathology from the biopsy specimen report confirms the diagnosis of colorectal cancer.

32. Adenomatous Polyp?

    When the biopsy report is normal mucosa or the polyp is a small (5 mm or less) left-sided hyperplastic polyp, return to screening activities and intervals as per the Screening Algorithm. Patient education and communication should occur at this time.

    There is emerging evidence that large (greater than 5 mm) hyperplastic polyps on the right side of the colon may have malignant potential. Colonoscopic follow-up of these patients may be indicated. At present, there are no clear evidence-based guidelines regarding management of these patients.

    Adenomatous polyps should be removed as part of the colonoscopy procedure. Confirmation of the presence of adenomatous polyps places the patient in an increased risk group. Such patients should be followed according to the increased risk surveillance protocol. (See Annotation #5, "Increased Risk Surveillance.")

33. Refer to Increased Risk Surveillance (Annotation #5)

    Due to the precancerous nature of certain adenomatous polyps, patients with such polyps should be monitored more closely than patients in the Screening Algorithm, and are outside the scope of this guideline.

34. Care Management: Out of Guideline

    Management of confirmed colorectal cancer is beyond the scope of this guideline and should be undertaken via appropriate specialty referral and care management.

Definitions:

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with

negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

   Class A:

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   Class B:

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   Class C:

   - Nonrandomized trial with concurrent or historical controls
   - Case-control study
   - Study of sensitivity and specificity of a diagnostic test
   - Population-based descriptive study

   Class D:

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   - Case series
   - Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

   Class M:

   - Meta-analysis

- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

CLINICAL ALGORITHM(S)

Two detailed and annotated clinical algorithms are provided for:

- Screening
- Flexible Sigmoidoscopy/Total Colon Evaluation (TCE)

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Decreased mortality from colorectal cancer due to earlier detection

POTENTIAL HARMS

- Colonoscopy. Colonoscopy involves a higher risk of perforation than flexible sigmoidoscopy. If conscious sedation is used, there is a risk of complications related to medication as well as a requirement for a period of post-procedure recovery and providing a driver for transport home after the procedure.
- False positive screening tests. The specificity of a positive fecal occult blood test is low. Numerous case studies report a very high rate (60% to 80%) of false positives.

- False negative screening tests. Fecal occult blood tests (FOBTs), even when combined with flexible sigmoidoscopy, fail to detect colorectal cancer in at least 24% of those with cancer.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This medical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.
- Evidence from randomized controlled studies alone is insufficient to determine which screening test (flexible sigmoidoscopy or fecal occult blood test) produces greater benefit (or if both are more beneficial than either alone). However, the value of either in detecting colorectal cancer or adenomatous polyps has been proven. At this time, the choice of using one (or both) of these tests should be made on the judgment of the clinician, taking into account other significant factors discussed in the original guideline document, including informed patient choice. In particular, attention is directed to the high rate of false-positive fecal occult blood tests and the failure of flexible sigmoidoscopy alone to screen the entire colon. As yet unproven is which screening test leads to the most efficient and effective use of colonoscopy. One study shows that one time combined screening fails to detect 24% of advanced colonic neoplasia. The guideline work group does not see sufficient evidence to reach absolute consensus as to which screening test is preferable, but does advocate screening by one of the four methods delineated. In recommending choice, the work group is basically in accord with the recommendations of the United States Preventive Services Task Force and the National Institutes of Health (NIH).
- There are no studies evaluating whether screening by barium enema alone reduces mortality from colorectal cancer in people at average risk for the disease. This option is based on evidence that screening double contrast barium enemas (DCBEs) can image the entire colon and detect cancers and large polyps almost as well as colonoscopy or flexible sigmoidoscopy.
- There is no evidence of reduction of colorectal cancer mortality in an average risk population by randomized trial, nonrandomized trial, or case-control studies through the use of colonoscopy. Colonoscopy, which can visualize the entire colon, is analogous in performance to flexible sigmoidoscopy, which has been shown to reduce colorectal cancer mortality.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Establish processes for both identifying age-appropriate individuals who have not undergone appropriate screening and contacting these patients to encourage them to do so (examples may include chart reminders, computer-generated reminder letters, etc.)

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources
Pocket Guide/Reference Cards
Quality Measures

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NQMC MEASURES

- Colorectal cancer screening: percentage of patients age 50 to 80 who are seen in the last month and who are up-to-date with respect to screening for colorectal cancer.
- Colorectal cancer screening: percentage of African American patients age 45 to 80 who are seen in the last month and who are up-to-date with respect to screening for colorectal cancer.
- Colorectal cancer screening: percentage of patients age 50 to 80 with counseling on colorectal cancer screening documented in the medical record, whether or not the screening test was done.

- Colorectal cancer screening: percentage of African American patients age 45 to 80 with counseling on colorectal cancer screening documented in the medical record, whether or not the screening test was done.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Colorectal cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jun. 50 p. [71 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1995 May (revised 2006 Jun)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family

Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

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GUIDELINE COMMITTEE

Preventive Services Steering Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: John Mageli, MD (Work Group Leader) (Aspen Medical Group) (Internal Medicine); Scott Boyers, MD (Sioux Valley Hospital and Health System) (Family Medicine); Michael Crandell, MD (Sioux Valley Hospitals and Health System) (Family Medicine); Irshad Jafri, MD (HealthPartners Medical Group) (Gastroenterology); Theresa Smith, MD (St. Mary's/Duluth Clinic Health Systems) (Gastroenterology); John Barlow, MD (Mayo Clinic) (Radiology); Penny Fredrickson (Institute for Clinical Systems Improvement) (Measurement Advisor/Implementation Advisor); Melissa Marshall, MBA (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Colorectal cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Jun. 57 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Colorectal cancer screening. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2006 Jun. 1 p. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.
- ICSI pocket guidelines. April 2006 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2006. 298 p.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

The following is available:

- Colorectal cancer screening. Health care guideline for patients and families. Bloomington (MN): Institute for Clinical Systems Improvement, 2006 Jun. 17 p. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

NGC STATUS

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